# General

## Guideline Title

American Academy of Orthopaedic Surgeons clinical practice guideline on detection and nonoperative management of pediatric developmental dysplasia of the hip in infants up to six months of age.

## Bibliographic Source(s)

American Academy of Orthopaedic Surgeons (AAOS). American Academy of Orthopaedic Surgeons clinical practice guideline on detection and nonoperative management of pediatric developmental dysplasia of the hip in infants up to six months of age. Rosemont (IL): American Academy of Orthopaedic Surgeons (AAOS); 2014 Sep 5. 368 p. [84 references]

## Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

# Recommendations

## Major Recommendations

Definitions of the strength of recommendations (Strong, Moderate, Limited, and Consensus) and Strength Visual (****, ***, **, *) are provided at the end of the "Major Recommendations" field.

Note from the American Academy of Orthopaedic Surgeons (AAOS): The following is a summary of the recommendations of the AAOS Clinical Practice Guideline on Detection and Nonoperative Management of Pediatric Developmental Dysplasia of the Hip in Infants up to Six Months of Age. All readers of this summary are strongly urged to consult the full guideline and evidence report for this information. The AAOS work group is confident that those who read the full guideline and evidence report will see that the recommendations were developed using systematic evidence-based processes designed to combat bias, enhance transparency, and promote reproducibility.

This summary of recommendations is not intended to stand alone. Treatment decisions should be made in light of all circumstances presented by the patient. Treatments and procedures applicable to the individual patient rely on mutual communication between patient guardian, physician, and other healthcare practitioners.

Summary of Recommendations

Universal Ultrasound Screening

Moderate evidence supports not performing universal ultrasound screening of newborn infants. Strength of Recommendation: Moderate ***

Evaluation of Infants with Risk Factors for Developmental Dysplasia of the Hip (DDH)

Moderate evidence supports performing an imaging study before 6 months of age in infants with one or more of the following risk factors: breech presentation, family history, or history of clinical instability. Strength of Recommendation: Moderate ***

Imaging of the Unstable Hip

Limited evidence supports that the practitioner might obtain an ultrasound in infants less than 6 weeks of age with a positive instability examination to guide the decision to initiate brace treatment. Strength of Recommendation: Limited **

Imaging of the Infant Hip

Limited evidence supports the use of an anteroposterior (AP) pelvis radiograph instead of an ultrasound to assess DDH in infants beginning at 4 months of age. Strength of Recommendation: Limited **

Surveillance after Normal Infant Hip Exam

Limited evidence supports that a practitioner re-examine infants previously screened as having a normal hip examination on subsequent visits prior to 6 months of age. Strength of Recommendation: Limited **

Stable Hip with Ultrasound Imaging Abnormalities

Limited evidence supports observation without a brace for infants with a clinically stable hip with morphologic ultrasound imaging abnormalities. Strength of Recommendation: Limited **

Treatment of Clinical Instability

Limited evidence supports either immediate or delayed (2-9 weeks) brace treatment for hips with a positive instability exam. Strength of Recommendation: Limited **

Type of Brace for the Unstable Hip

Limited evidence supports use of the von Rosen splint over Pavlik, Craig, or Frejka splints for initial treatment of an unstable hip. Strength of Recommendation: Limited **

Monitoring of Patients during Brace Treatment

Limited evidence supports that the practitioner perform serial physical examinations and periodic imaging assessments (ultrasound or radiograph based on age) during management for unstable infant hips. Strength of Recommendation: Limited **

Definitions:

Strength of Recommendations Descriptions

| Strength | Overall Strength of Evidence | Description of Evidence Strength | Strength Visual |
|---|---|---|---|
| Strong | Strong | Evidence from two or more "High" strength studies with consistent findings for recommending for or against the intervention. | **** |
| Moderate | Moderate | Evidence from two or more "Moderate" strength studies with consistent findings, or evidence from a single "High" quality study for recommending for or against the intervention. | *** |
| Limited | Low Strength Evidence or Conflicting Evidence | Evidence from one or more "Low" strength studies with consistent findings or evidence from a single "Moderate" strength study for recommending for against the intervention or diagnostic or the evidence is insufficient or conflicting and does not allow a recommendation for or against the intervention. | ** |
| Consensus† | No Evidence | There is no supporting evidence. In the absence of reliable evidence, the work group is making a recommendation based on their clinical opinion. Consensus recommendations can only be created when not establishing a recommendation could have catastrophic consequences. | * |

†Consensus based recommendations are made according to specific criteria. These criteria can be found in Appendix VI in the original guideline document.

## Clinical Algorithm(s)

None provided

# Scope

## Disease/Condition(s)

Developmental dysplasia of the hip (DDH)

## Guideline Category

Diagnosis

Evaluation

Management

Risk Assessment

Screening

Treatment

## Clinical Specialty

Family Practice

Orthopedic Surgery

Pediatrics

Radiology

## Intended Users

Advanced Practice Nurses

Allied Health Personnel

Health Care Providers

Health Plans

Managed Care Organizations

Nurses

Patients

Physician Assistants

Physicians

## Guideline Objective(s)

- To provide practice recommendations for the early screening and detection of hip instability and dysplasia and also highlight gaps in the published literature that should stimulate additional research
- To improve the ability of practitioners to detect and manage hip instability and hip dysplasia in typically developing children less than 6 months of age based upon the current best evidence

## Target Population

Typically developing children less than 6 months of age

Note: The guideline is not intended for use for children who have teratologic hip abnormalities or hip abnormalities associated with neuromuscular, genetic, or acquired complex musculoskeletal or developmental abnormalities.

## Interventions and Practices Considered

Universal ultrasound screening (not recommended)
Imaging studies of infants with risk factors for developmental dysplasia of the hip (DDH)
Ultrasound imaging (infants less than 6 weeks of age with a positive instability examination)
Anteroposterior (AP) pelvis radiography
Surveillance after normal infant hip exam
Observation without a brace (infants with stable hip with ultrasound imaging abnormalities)
Brace treatment of clinical instability (von Rosen splint)
Monitoring of patients during brace treatment

## Major Outcomes Considered

- Detection of late-presenting developmental dysplasia of the hip (DDH)
- Treatment rate
- Prognostic value of family risk factors for DDH
- Sensitivity, specificity, and positive/negative predictive value of diagnostic modalities
- Rate of radiographically detected subluxation, dislocation, or acetabular dysplasia
- Avascular necrosis (AVN) rate
- Surgical treatment rate
- Rate of resolution of hip dysplasia
- Brace treatment failure (failure of reduction or persistent dysplasia)

# Methodology

## Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

## Description of Methods Used to Collect/Select the Evidence

Study Selection Criteria

The American Academy of Orthopaedic Surgeons (AAOS) work group developed *a priori* article inclusion criteria for the review. These criteria

are the "rules of evidence" and articles that did not meet them are, for the purposes of this guideline, not evidence.

To be included in the systematic reviews (and hence, in this guideline) an article had to be a report of a study that:

- Study must be of developmental dysplasia of the hip.
- Article must be a full article report of a clinical study.
- Study must appear in a peer-reviewed publication.
- Study must be published in English.
- Study must be published in or after 1950.
- Study must be of humans.
- Study must not be an in vitro study.
- Study must not be a biomechanical study.
- Study must not have been performed on cadavers.
- Study should have 10 or more patients per group.
- All study follow-up durations are included.
- Study results must be quantitatively presented.
- For any given follow-up time point in any included study, there must be ≥50% patient follow-up.
- Retrospective non-comparative case series, medical records review, meeting abstracts, historical articles, editorials, letters, and commentaries are excluded.
- Case series studies that give patients the treatment of interest AND another treatment are excluded.
- Case series studies that have non-consecutive enrollment of patients are excluded.
- All studies of "Very Low" strength of evidence are excluded.
- Quantitatively presented results.

When a study's "duration of symptoms" is not the same as those examined by the work group (i.e., 0-2 weeks, 2-6 weeks, etc.) the study will be assigned to the appropriate "duration of symptoms" group based upon the mean duration of symptoms. If a range rather than mean is provided, the higher end of the range will dictate which "duration of symptoms" group the study will be assigned to. For example, a study reporting patient symptoms of 0-4 weeks would be included in the time frame "2-6 weeks" created by the work group.

Systematic reviews or meta-analyses compiled by others or guidelines developed by other organizations were not included. These documents are developed using different inclusion criteria than those specified by the AAOS work group. Therefore they may include studies that do not meet AAOS inclusion criteria. These documents were recalled if the abstract suggested they might provide an answer to one of the work group's recommendations, and their bibliographies were searched for additional studies to supplement the systematic review.

Literature Searches

The guideline developers began the systematic review with a comprehensive search of the literature. Articles considered were published prior to May 2012 in four electronic databases; PubMed, EMBASE, CINAHL, and The Cochrane Central Register of Controlled Trials. The medical librarian conducted the search using key terms determined from the work group's preliminary recommendations.

The electronic search was supplemented with a manual search of the bibliographies of all retrieved publications, recent systematic reviews, and other review articles for potentially relevant citations. Recalled articles were evaluated for possible inclusion based on the study selection criteria and were summarized for the work group who assisted with reconciling possible errors and omissions.

The study attrition diagram in Appendix III in the original guideline document provides a detailed description of the numbers of identified abstracts and recalled and selected studies that were evaluated in the systematic review of the guideline. The search strategies used to identify the abstracts are contained in Appendix IV in the original guideline document.

## Number of Source Documents

31 articles were included (see the Study Attrition Flowchart in Appendix III in the original guideline document).

## Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

# Rating Scheme for the Strength of the Evidence

Methods for Evaluating Evidence

Studies of Intervention/Prevention

*Quality*

The American Academy of Orthopaedic Surgeons (AAOS) judges quality based on *a priori* research questions and uses an automated numerical scoring process to arrive at final ratings. Extensive measures are taken to determine quality ratings so that they are free of bias.

The quality of evidence is evaluated separately for each outcome reported in every study using research design domains suggested by Grading of Recommendations Assessment, Development and Evaluation (GRADE) work group members and others. The GRADE evidence appraisal system is used in the Cochrane Collaboration and has been developed for studies evaluating matched control groups. A coding scheme adaptable to all research designs is incorporated that involves incremental increases or decreases based on the following criteria:

- The study was prospective (with prospective studies, it is possible to have an *a priori* hypothesis to test; this is not possible with retrospective studies)
- The statistical power of the study
- The assignment of patients to groups was unbiased
- There was sufficient blinding to mitigate against a placebo effect
- The patient groups were comparable at the beginning of the study
- The treatment was delivered in such a way that any observed effects could reasonably be attributed to that treatment
- Whether the instruments used to measure outcomes were valid
- Whether there was evidence of investigator bias

Each of the above quality domains is rated for possible flaws based on up to four indicator questions that define them. See Appendix V in the original guideline document for a discussion of the AAOS appraisal system. Domains are considered "flawed" if one indicator is coded "No" or at least two defining questions are "Unclear." The Statistical Power domain is considered flawed if sample size is too small to detect at least a small effect size of 0.2.

If there are flawed domains then the evidence quality is downgraded according to the reductions shown in the table below. As an example, the evidence reported in a randomized controlled trial (RCT) for any given outcome is rated as "High" quality if zero or one domain is flawed. If two or three domains are flawed, the rating is reduced to "Moderate." If four or five domains are flawed, the quality of evidence is downgraded to "Low." The quality of evidence is reduced to "Very Low" if six or more domains are flawed. As indicated above, very low quality evidence is not included in this AAOS guideline.

Relationship between Quality and Domain Scores for Interventions

| Number of Domains with No More Than One "Unclear" Answer | Strength of Evidence |
|---|---|
| 0 | High |
| 1-2 | Moderate |
| 3-4 | Low |
| >5 | Very low |

Some flaws are so serious that the evidence is automatically termed as being of "Very Low" quality if a study exhibits them. These serious design flaws are:

- Non-consecutive enrollment of patients in a case series
- Case series that gave patients the treatment of interest AND another treatment
- Measuring the outcome of interest one way in some patients and measuring it in another way in other patients
- Low statistical power

Conversely, the quality of research articles may be upgraded if the research is of high applicability or if providing the intervention decreases the potential for catastrophic harm, such as loss of life or limb. The criteria, based on the GRADE methodology, which can be used to upgrade the

quality of a study, are as follows:

- The study has a large (>2) or very large (>5) magnitude of treatment effect: used for non-retrospective observational studies;
- All plausible confounding factors would reduce a demonstrated effect or suggest a spurious effect when results show no effect;
- Consideration of the dose-response effect.

Quality is one of two dimensions that determine the strength of the final recommendations.

*Applicability*

The applicability (also called "generalizability" or "external validity") of an outcome is one of the factors used to determine the strength of a recommendation. Outcomes are categorized according to whether their applicability is "High", "Moderate", or "Low." As with quality, the applicability for each outcome a study reports is separately evaluated.

The applicability of a study is evaluated using the pragmatic-explanatory continuum indicator summary (PRECIS) instrument. The instrument was originally designed to evaluate the applicability of randomized controlled trials, but it can also be used for studies of other design. For example, the existence of an implicit control group in a case series (see above) make it useful for evaluating outcomes from these latter studies.

This instrument is comprised of the 10 questions that are briefly described in Table 2 in the original guideline document. All 10 questions are asked of all studies, regardless of design. The questions are divided into four domains. These domains and their corresponding questions are given in Table 2 in the original guideline document.

Each study is assumed to have "High" applicability at the start, and applicability is downgraded for flawed domains as summarized in the table below.

Relationship between Applicability and Domain Scores for Studies of Treatments

| Number of Flawed Domains | Applicability |
|---|---|
| 0 | High |
| 1,2,3 | Moderate |
| 4 | Low |

A study's applicability is "High" if there is only one "Unclear" answer in one domain and the answers to all of the questions for all other domains is "Yes." A study's applicability is low if there is one "Unclear" answer in one domain and the answers to all of the questions for all other domains is "No." A study's applicability is "Moderate" under all other conditions.

Refer to Section III in the original guideline document for a description of the methods used to determine the quality and applicability of evidence for the following types of studies:

- Studies of screening and diagnostic tests
- Studies of prognostics

Final Strength of Evidence

To determine the final strength of evidence for an outcome, the strength is initially taken to equal quality. An outcome's strength of evidence is increased by one category if its applicability is "High", and an outcome's strength of evidence is decreased by one category if its applicability is "Low." If an outcome's applicability is "Moderate", no adjustment is made to the strength of evidence derived from the quality evaluation.

## Methods Used to Analyze the Evidence

Meta-Analysis

Systematic Review with Evidence Tables

## Description of the Methods Used to Analyze the Evidence

Best Evidence Synthesis

When determining the best available evidence, the highest-strength studies available for the outcomes examined are included first. If there are two or more high-strength studies, the recommendation grade is strong. In this case, moderate- and low- strength evidence do not influence the grade of the recommendation. If there is one high- or at least two moderate- strength studies, the recommendation grade is moderate. If there is one moderate- or at least one low- strength studies, the recommendation grade is limited. Consensus based recommendations are established only when the rules for consensus recommendations apply. A summary of the evidence that met the initial inclusion criteria, but was not best available evidence was created for each recommendation and can be viewed by recommendation in Appendix XII of the original guideline document.

Statistical Methods

Analysis of Diagnostic Data

Likelihood ratios (LR), sensitivity, specificity and 95% confidence intervals were calculated to determine the accuracy of diagnostic modalities based on two by two diagnostic contingency tables extracted from the included studies. When summary values of sensitivity, specificity, or other diagnostic performance measures were reported, estimates of the diagnostic contingency table were used to calculate LR. LR indicate the magnitude of the change in probability of disease due to a given test result. For example, a positive LR of 10 indicates that a positive test result is 10 times more common in patients with disease than in patients without disease. LR are interpreted according to previously published values, as seen in Table 11 in the original guideline document.

Analysis of Intervention/Prevention Data

When possible, the results reported in individual studies are recalculated and compiled to answer the recommendations. The results of all statistical analysis conducted by the American Academy of Orthopaedic Surgeons (AAOS) Clinical Practice Guidelines Unit are conducted using STATA 12. STATA was used to determine the magnitude, direction, and/or 95% confidence intervals of the treatment effect. For data reported as means (and associated measures of dispersion) the mean difference between groups and the 95% confidence interval was calculated and a two-tailed t-test of independent groups was used to determine statistical significance. When published studies report measures of dispersion other than the standard deviation the value was estimated to facilitate calculation of the treatment effect. In studies that report standard errors or confidence intervals the standard deviation was back-calculated. In some circumstances statistical testing was conducted by the authors and measures of dispersion were not reported. In the absence of measures of dispersion, the results of the statistical analyses conducted by the authors (i.e., the p-value) are considered as evidence. For proportions, the proportion of patients that experienced an outcome along with the percentage of patients that experienced an outcome is reported. The variance of the arcsine difference was used to determine statistical significance. P-values $<0.05$ were considered statistically significant.

Meta-analyses were performed using the random effects method of DerSimonian and Laird. A minimum of four studies was required for an outcome to be considered by meta-analysis. Heterogeneity was assessed with the I-squared statistic. Meta-analyses with I-squared values less than 50% were considered as evidence. Those with I-squared larger than 50% were not considered as evidence for this guideline. All meta-analyses were performed using STATA 12 and the "metan" command. The arcsine difference was used in meta-analysis of proportions. In order to overcome the difficulty of interpreting the magnitude of the arcsine difference, a summary odds ratio is calculated based on random effects meta-analysis of proportions and the number needed to treat (or harm) is calculated. The standardized mean difference was used for meta-analysis of means and magnitude was interpreted using Cohen's definitions of small, medium, and large effect.

## Methods Used to Formulate the Recommendations

Expert Consensus

## Description of Methods Used to Formulate the Recommendations

This guideline and systematic review were prepared by the American Academy of Orthopaedic Surgeons (AAOS) Developmental Dysplasia of the Hip guideline clinician work group (clinical experts) with the assistance of the AAOS Evidence-Based Medicine (EBM) Unit in the Department of Research and Scientific Affairs (methodologists) at the AAOS. To develop this guideline, the work group held an introductory meeting on June 11-12, 2011 to establish the scope of the guideline and the systematic reviews. The clinical experts defined the scope of the guideline by creating preliminary recommendations (Questions) that directed the literature search. When necessary, these clinical experts also provided content help, search terms and additional clarification for the AAOS Medical Librarian. The Medical Librarian created and executed the search(s). The supporting group of methodologists (AAOS EBM Unit) reviewed all abstracts, recalled pertinent full-text articles for review and evaluated the quality of studies meeting the inclusion criteria. They also abstracted, analyzed, interpreted, and/or summarized the relevant evidence for each

recommendation and prepared the initial draft for the final meeting. Upon completion of the systematic reviews, the clinician work group participated in a three-day recommendation meeting on October 4-6, 2013. At this meeting, the clinician experts and methodologists then evaluated and integrated all material to develop the final recommendations. The final recommendations and rationales were edited, written, and voted on at the final meeting. The draft guideline recommendations and rationales received final review by the methodologists to ensure that these recommendations and rationales were consistent with the data. The draft was then completed and submitted for peer review on April 14, 2014.

Formulating Preliminary Recommendations

The work group began work on this guideline by constructing a set of preliminary recommendations. These recommendations specify [what] should be done in [whom], [when], [where], and [how often or how long]. They function as questions for the systematic review, not as final recommendations or conclusions. Preliminary recommendations are almost always modified on the basis of the results of the systematic review. Once established, these *a priori* preliminary recommendations cannot be modified until the final work group meeting.

Defining the Strength of the Recommendations

Judging the strength of evidence is only a stepping stone towards arriving at the strength of a guideline recommendation. The strength of recommendation also takes into account the quality, quantity, and the trade-off between the benefits and harms of a treatment, the magnitude of a treatment's effect, and whether there is data on critical outcomes.

Strength of recommendation expresses the degree of confidence one can have in a recommendation. As such, the strength expresses how possible it is that a recommendation will be overturned by future evidence. It is very difficult for future evidence to overturn a recommendation that is based on many high quality randomized controlled trials that show a large effect. It is much more likely that future evidence will overturn recommendations derived from a few small case series. Consequently, recommendations based on the former kind of evidence are given a high strength of recommendation and recommendations based on the latter kind of evidence are given a low strength.

To develop the strength of a recommendation, AAOS staff first assigned a preliminary strength for each recommendation that took only the final strength of evidence (including quality and applicability) and the quantity of evidence (see the "Rating Scheme for the Strength of the Recommendations" field).

Wording of the Final Recommendations

To prevent bias in the way recommendations are worded, the AAOS uses specific predetermined language stems that are governed by the evidence strengths. Each recommendation was written using language that accounts for the final strength of the recommendation. This language, and the corresponding strength, is shown in Table 9 in the original guideline document.

Voting on the Recommendations

Recommendations were voted on by the work group members during the final meeting. If disagreement among the work group occurred, there was further discussion to see whether the disagreement(s) could be resolved. Up to three rounds of voting were held to attempt to resolve disagreements. If disagreements were not resolved following three voting rounds, no recommendation was adopted. Lack of agreement is a reason that the strength for some recommendations can be labeled "Limited."

## Rating Scheme for the Strength of the Recommendations

Strength of Recommendations Descriptions

| Strength | Overall Strength of Evidence | Description of Evidence Strength | Strength Visual |
|---|---|---|---|
| Strong | Strong | Evidence from two or more "High" strength studies with consistent findings for recommending for or against the intervention. | **** |
| Moderate | Moderate | Evidence from two or more "Moderate" strength studies with consistent findings, or evidence from a single "High" quality study for recommending for or against the intervention. | *** |
| Limited | Low Strength Evidence or | Evidence from one or more "Low" strength studies with consistent findings or evidence from a single "Moderate" strength study for recommending for against the intervention or diagnostic or | ** |

| Overall Strength of Evidence | Description of Evidence Strength | Visual Strength |
|---|---|---|
| Conflicting Evidence | the evidence is insufficient or conflicting and does not allow a recommendation for or against the intervention. | |
| No Evidence | There is no supporting evidence. In the absence of reliable evidence, the work group is making a recommendation based on their clinical opinion. Consensus recommendations can only be created when not establishing a recommendation could have catastrophic consequences. | * |
| Strength Consensus† | | |

†Consensus based recommendations are made according to specific criteria. These criteria can be found in Appendix VI in the original guideline document.

## Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

## Method of Guideline Validation

External Peer Review

Internal Peer Review

## Description of Method of Guideline Validation

Peer Review

Following the final meeting, the guideline draft undergoes peer review for additional input from external content experts. Written comments are provided on the structured review form (see Appendix VII in the original guideline document). All peer reviewers are required to disclose their conflicts of interest. To guide who participates, the work group identifies specialty societies at the introductory meeting. Organizations, not individuals, are specified.

The specialty societies are solicited for nominations of individual peer reviewers approximately six weeks before the final meeting. The peer review period is announced as it approaches and others interested are able to volunteer to review the draft. The chair of the American Academy of Orthopaedic Surgeons (AAOS) Committee on Evidence Based Quality and Value reviews the draft of the guideline prior to dissemination.

Some specialty societies (both orthopaedic and non-orthopaedic) ask their evidence-based practice (EBP) committee to provide review of the guideline. The organization is responsible for coordinating the distribution of materials and consolidating their comments onto one form. The chair of the external EBP committees provides disclosure of their conflicts of interest (COI) and manages the potential conflicts of their members.

Again, the AAOS asks for comments to be assembled into a single response form by the specialty society and for the individual submitting the review to provide disclosure of potentially conflicting interests. The peer review stage gives external stakeholders an opportunity to provide evidence-based direction for modifications that they believe have been overlooked. Since the draft is subject to revisions until its approval by the AAOS Board of Directors as the final step in the guideline development process, confidentiality of all working drafts is essential.

The manager of the evidence-based medicine unit drafts the initial responses to comments that address methodology. These responses are then reviewed by the work group chair and vice-chair, who respond to questions concerning clinical practice and techniques. The director of the Department of Research and Scientific Affairs provides input as well. All comments received and the initial drafts of the responses are also reviewed by all members of the work group. All changes to a recommendation as a result of peer review are based on the evidence and undergoes majority vote by the work group members via teleconference. Final revisions are summarized in a detailed report that is made part of the guideline document throughout the remainder of the review and approval processes.

The AAOS believes in the importance of demonstrating responsiveness to input received during the peer review process and welcomes the critiques of external specialty societies. Following final approval of the guideline, all individual responses are posted on the AAOS Web site with a point-by-point reply to each non-editorial comment. Reviewers who wish to remain anonymous notify the AAOS to have their names de-identified; their comments, our responses, and their COI disclosures are still posted.

Review of the Management of Developmental Dysplasia of the Hip guideline was requested of 25 organizations and 27 external content experts

were nominated to represent them. Fifteen individuals returned comments on the structured review form (see Appendix VIII in the original guideline document).

Public Commentary

After modifying the draft in response to peer review, the guideline was subjected to a thirty day period of "Public Commentary." Commentators consist of members of the AAOS Board of Directors (BOD), members of the Council on Research and Quality (CORQ), members of the Board of Councilors (BOC), and members of the Board of Specialty Societies (BOS). The guideline is automatically forwarded to the AAOS BOD and CORQ so that they may review it and provide comment prior to being asked to approve the document. Members of the BOC and BOS are solicited for interest. If they request to see the document, it is forwarded to them for comment. Based on these bodies, over 200 commentators have the opportunity to provide input into this guideline. Of these five members returned public comments.

AAOS Guideline Approval Process

This final guideline draft must be approved by the AAOS Committee on Evidence-Based Quality and Value, the AAOS Council on Research and Quality, and the AAOS Board of Directors. These decision-making bodies are described in Appendix II in the original guideline document and are not designated to modify the contents. Their charge is to approve or reject its publication by majority vote.

The guideline was adopted by the American Academy of Orthopaedic Surgeons Board of Directors on September 5, 2014.

# Evidence Supporting the Recommendations

## Type of Evidence Supporting the Recommendations

The type of supporting evidence is specifically stated for each recommendation (see the "Major Recommendations" field).

# Benefits/Harms of Implementing the Guideline Recommendations

## Potential Benefits

Early diagnosis and appropriate nonoperative management of pediatric developmental dysplasia of the hip (DDH) in infants up to six months of age

## Potential Harms

Most treatments are associated with known risks. In the case of screening and early intervention programs, potential harms may be related to either over diagnosis with increased rates of further evaluation and treatment that may be unnecessary and to under diagnosis that can lead to a late diagnosis with progression of deformity. Clinician input based upon experience decreases the probability of harms in both scenarios.

Potential Harms of Specific Interventions

- Intervention with splintage devices, more frequent visits to providers and increased rates of imaging occur in observational and case control series where the diagnosis of developmental dysplasia of the hip (DDH) is given. Treatment of all forms for DDH has been associated with varying rates of avascular necrosis (AVN) that represent a possibility of harm to individual patients.
- Observational and case control studies suggest that the management of children who present with DDH at walking age or older has greater risk of being managed by open surgical hip reduction with its attendant risks of AVN, infection, hip stiffness, and early onset osteoarthritis as an adult.
- The emotional impact upon a family of detecting a non-apparent musculoskeletal problem in a newborn is unknown. There may be emotional impact upon parents who are given false positive screening information.
- There is a potential to miss a case of DDH in an infant with a normal clinical examination and no risk factors. This could lead to a late diagnosis with concerns for a potential of higher rate of treatment complications as a result of late diagnosis.
- Radiographs involve exposure to ionizing radiation.
- In one published study, 19% of the patients treated with rigid braces experienced skin irritation. There is a potential risk of AVN with all bracing; the relative risk is unknown between rigid and soft bracing.

- With imaging studies there is a potential risk of over diagnosis and treatment.

# Qualifying Statements

## Qualifying Statements

- This Clinical Practice Guideline was developed by an American Academy of Orthopaedic Surgeons (AAOS) clinician volunteer Work Group based on a systematic review of the current scientific and clinical information and accepted approaches to treatment and/or diagnosis. This Clinical Practice Guideline is not intended to be a fixed protocol, as some patients may require more or less treatment or different means of diagnosis. Clinical patients may not necessarily be the same as those found in a clinical trial. Patient care and treatment should always be based on a clinician's independent medical judgment, given the individual patient's clinical circumstances.
- The summary of recommendations is not intended to stand alone. Treatment decisions should be made in light of all circumstances presented by the patient. Treatments and procedures applicable to the individual patient rely on mutual communication between patient guardian, physician, and other healthcare practitioners.
- Some drugs or medical devices referenced or described in this Clinical Practice Guideline may not have been cleared by the U.S. Food and Drug Administration (FDA) or may have been cleared for a specific use only. The FDA has stated that it is the responsibility of the physician to determine the FDA clearance status of each drug or device he or she wishes to use in clinical practice.
- Many different providers may provide musculoskeletal care in many different settings. This guideline was created as an educational tool to guide qualified practitioners through a series of treatment decisions in an effort to improve the quality and efficiency of care. This guideline should not be construed as including all proper methods of care or excluding methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure of treatment must be made in light of all circumstances presented by the patient and the needs and resources particular to the locality or practice setting.

# Implementation of the Guideline

## Description of Implementation Strategy

Guideline Dissemination Plans

The primary purpose of the guideline is to provide interested readers with full documentation about not only the work group's recommendations, but also about how the group arrived at those recommendations. This document is also posted on the American Academy of Orthopaedic Surgeons (AAOS) website .

Shorter versions of the guideline are available in other venues. Publication of most guidelines is announced by an Academy press release, articles authored by the work group and published in the Journal of the American Academy of Orthopaedic Surgeons, and articles published in AAOS *Now*. Most guidelines are also distributed at the AAOS Annual Meeting in various venues such as on Academy Row and at Committee Scientific Exhibits.

Selected guidelines are disseminated by webinar, an Online Module for the Orthopaedic Knowledge Online website, Radio Media Tours, Media Briefings, and by distributing them at relevant Continuing Medical Education (CME) courses and at the AAOS Resource Center.

Other dissemination efforts outside of the AAOS will include submitting the guideline to the National Guideline Clearinghouse (NGC) and distributing the guideline at other medical specialty societies' meetings.

## Implementation Tools

Quick Reference Guides/Physician Guides

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

# Institute of Medicine (IOM) National Healthcare Quality Report Categories

## IOM Care Need

Getting Better

Staying Healthy

## IOM Domain

Effectiveness

# Identifying Information and Availability

## Bibliographic Source(s)

American Academy of Orthopaedic Surgeons (AAOS). American Academy of Orthopaedic Surgeons clinical practice guideline on detection and nonoperative management of pediatric developmental dysplasia of the hip in infants up to six months of age. Rosemont (IL): American Academy of Orthopaedic Surgeons (AAOS); 2014 Sep 5. 368 p. [84 references]

## Adaptation

Not applicable: The guideline was not adapted from another source.

## Date Released

2014 Sep 5

## Guideline Developer(s)

American Academy of Orthopaedic Surgeons - Medical Specialty Society

## Source(s) of Funding

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## Financial Disclosures/Conflicts of Interest

In accordance with American Academy of Orthopaedic Surgeons (AAOS) policy, all individuals whose names appear as authors or contributors to Clinical Practice Guideline filed a disclosure statement as part of the submission process. All panel members provided full disclosure of potential conflicts of interest prior to voting on the recommendations contained within this Clinical Practice Guidelines. See Appendix IX in the original guideline document for individual work group members' conflicts of interest.

## Guideline Endorser(s)

American Academy of Pediatrics - Medical Specialty Society

Pediatric Orthopaedic Society of North America - Medical Specialty Society

Society for Pediatric Radiology - Medical Specialty Society

Society of Diagnostic Medical Sonography - Professional Association

## Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

## Guideline Availability

Electronic copies: Available from American Academy of Orthopaedic Surgeons Web site .

Print copies: Available from the American Academy of Orthopaedic Surgeons, 9400 West Higgins Road, Rosemont, IL 60018-4262. Telephone: (800) 626-6726 (800 346-AAOS); Fax: (847) 823-8125; Web site: www.aaos.org .

## Availability of Companion Documents

The following is available:

- Detection and nonoperative management of pediatric developmental dysplasia of the hip in infants up to six months of age. Summary of recommendations. Rosemont (IL): American Academy of Orthopaedic Surgeons; 2014. 9 p. Electronic copies: Available from the American Academy of Orthopaedic Surgeons Web site .

## Patient Resources

None available

## NGC Status

This NGC summary was completed by ECRI Institute on October 21, 2014. The information was verified by the guideline developer on November 14, 2014.

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